



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1289B

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: FDA Sample No. 3109760
Customs Entry No. DM1-0044294-4
Product: Greenhouse Tomatoes

WARNING LETTER

FLA-97-32

March 25, 1997

Mr. Tom Lange
Owner, Tom Lange (Canada), Inc.
165 The Queen's Way
Toronto, Ontario, Canada

Dear Mr. Lange

The Food and Drug Administration (FDA) attempted to examine a shipment of greenhouse tomatoes offered for entry into the United States by your firm on March 16, 1997, under the above referenced entry number, and found the shipment was not held intact for FDA examination. Regulations, Title 21, Code of Federal Regulations (CFR), Part 1.90, requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We have requested the U. S. Customs Service (Customs) to order redelivery of this shipment (copy enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of further shipments. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation.

Mr. Tom Lange
Page 2
March 25, 1997

Your written reply should be addressed to the Food and Drug Administration, Attention: Paul R. Bagdikian, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,



Douglas D. Tolen
Director, Florida District

Enclosure

cc: Beth Craig & Associates, Inc.
8280 N.W. 27th St., #503
Miami, Florida 33122